

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5347]

Draft “Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Intimate Contacts;” Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled “Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Intimate Contacts” dated February 2002. The draft guidance document provides recommendations to all registered blood and plasma establishments, and establishments engaged in manufacturing plasma derivatives. The draft guidance document, when finalized, is intended to provide recommendations regarding the disposition of blood products manufactured from a donor who is retrospectively discovered to have received a xenotransplantation product or to have been an intimate contact of a xenotransplantation product recipient. This is the second draft guidance document and it incorporates revisions based on public comments received on the first draft guidance document by the same name announced in the **Federal Register** of December 30, 1999 (64 FR 73562).

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by *[insert date 90 days after date of publication in the **Federal Register**]*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Michael D. Anderson, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised, second draft document entitled “Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Intimate Contacts” dated February 2002. The draft guidance document provides FDA’s recommendations to all registered blood and plasma establishments, and establishments engaged in manufacturing plasma derivatives. The draft guidance document, when finalized, is intended to provide recommendations regarding the disposition of blood products manufactured from a donor who is retrospectively discovered to have received a xenotransplantation product or to have been an intimate contact of a xenotransplantation product recipient. This second draft guidance document incorporates revisions based on public comments received on the first draft document by the same

name announced in the **Federal Register** of December 30, 1999, due to the number of changes made to the previous version of the draft guidance.

FDA issues this draft guidance consistent with the good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking on precautionary measures to reduce the possible risk of transmission of zoonoses by xenotransplantation product recipients and their contacts, through blood and blood products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

FDA is distributing this draft document for comment purposes only and does not intend to implement the draft guidance at this time. To ensure adequate consideration in preparation of the final document, interested persons may submit written comments to the Dockets Management Branch (address above) by [*insert date 90 days after date of publication in the **Federal Register***]. Submit two copies of any comments, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cber/guidelines.htm>.

Dated: _____

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